EU Technical Documentation Assessment Certificate

We hereby certify that the company

PRIMA Lab SA
Viale Serfontana 10
6834 Morbio Inferiore
Switzerland

has submitted a technical documentation in accordance with Annexes II and III of Regulation (EU) 2017/746, which meets the following requirements:

Annex IX – Chapter II (Assessment of the Technical Documentation)

of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.

Considering the specific requirements for devices for self-testing and near-patient testing of Section 5.1.

This certificate from mdc medical device certification GmbH (Notified Body 0483) consists of 3 pages. Details of the devices covered as well as further information and conditions are contained on the following pages.

Valid from	2026-07-14	Registration No.	D1408400113
Valid until	2028-10-25	Report No.	P26-00347-366252

Stuttgart, 2026-07-14

Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-098

EU Authorized Representative:

QbD RepS BV
Groenenborgerlaan 16
2610 Wilrijk
Belgium
BE-AR-000000040

Devices:

Celiac Disease Screening Test (REF CE2H88000KIT01EN, CE2H88000KIT01IT, CE2H88000BAG01EN, CE2H88000BAG01IT, CE2H88000KIT01E5, CE2H88100KIT01EP, CE2H88B00KIT01HU, CE2H8PR00KIT01IT, CE2H88000BAG01ED)

Intended purpose: Rapid immunochromatographic manual self-test for the qualitative detection of anti-Deamidated Gliadin Peptide IgG and anti-tissue Transglutaminase IgA in human capillary blood sample for the screening of celiac disease

Risk class: C self-testing
IVS 1002 Devices intended to be used for self-testing
Basic UDI-DI: 764016486CE2H867

EARLY DETECTION PREGNANCY TEST (REF: HGEH88000KIT01EN, HGEH88000KIT02EN, HGEH88000KIT02E5, HGEH88000KIT02IT, HGEH88000KIT01IT, HGEH88B00KIT02HU, HGEH88B00KIT01HU)

SANAVITA TEST Gravidanza - EARLY DETECTION PREGNANCY TEST (REF: HGEH8SV00KIT01IT)

First Praedict TEST DI GRAVIDANZA PRECOCE (REF: HGEH8FP00KIT02IT)

Intended purpose: Rapid Immunochromatographic manual self-test for the qualitative detection of the chorionic gonadotropin hormone (hCG) in human urine as an aid to the early identification of the pregnancy status in women.

Risk class: B self-testing
IVS 1002 Devices intended to be used for self-testing
Basic UDI-DI: 764016486HGEH8B6

Notes:

For the placing on the market of the devices an EU Quality Management System Certificate according to Annex IX, Chapter I of Regulation (EU) 2017/746 on in vitro diagnostic medical devices is also required.

The certificate is based on the previous certificate

D1408400090 (2024-09-24)
D1408400100 (2025-07-15)
D1408400103 (2025-09-11)
D1408400105 (2025-11-14)
D1408400111 (2026-04-29)

with the following changes to D1408400111:
Supplemented by:
SANAVITA TEST Gravidanza - EARLY DETECTION PREGNANCY TEST (REF: HGEH8SV00KIT01IT)
First Praedict TEST DI GRAVIDANZA PRECOCE (REF: HGEH8FP00KIT02IT)